

Title: Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes

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19 **Abstract**

20 *Background*

21 There is no consensus on the precise rocker shoe outsole design that will optimally reduce
22 plantar pressure in people with diabetes. This study aimed to understand how peak plantar
23 pressure is influenced by systematically varying three design features which characterise a
24 curved rocker shoe: apex angle, apex position and rocker angle.

25 *Methods*

26 A total of 12 different rocker shoe designs, spanning a range of each of the three design
27 features, were tested in 24 people with diabetes and 24 healthy participants. Each subject also
28 wore a flexible control shoe. Peak plantar pressure, in four anatomical regions, was recorded
29 for each of the 13 shoes during walking at a controlled speed.

30 *Findings*

31 There were a number of significant main effects for each of the three design features,
32 however, the precise effect of each feature varied between the different regions. The results
33 demonstrated maximum pressure reduction in the 2nd-4th metatarsal regions (39%) but that
34 lower rocker angles (<20°) and anterior apex positions (> 60% shoe length) should be
35 avoided for this region. The effect of apex angle was most pronounced in the 1st
36 metatarsophalangeal region with a clear decrease in pressure as the apex angle was increased
37 to 100°.

38 *Interpretation*

39 We suggest that an outsole design with a 95° apex angle, apex position at 60% of shoe length
40 and 20° rocker angle may achieve an optimal balance for offloading different regions of the

41 forefoot. However, future studies incorporating additional design feature combinations, on
42 high risk patients, are required to make definitive recommendations.

43 **Keywords:** Rocker shoe, Footwear, Plantar pressure, diabetes.

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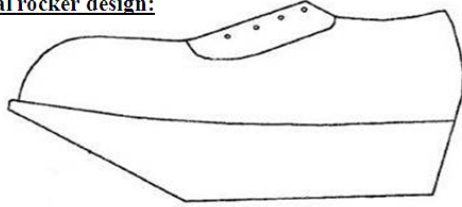
Introduction

Specially designed footwear is often prescribed to patients with diabetes to reduce in-shoe pressures (Cavanagh et al., 2000). Prospective clinical trials have demonstrated that therapeutic footwear can reduce the incidence of foot ulcers (Chantelau, 2004; Uccioli et al., 1995), however, further research is required to understand whether pressure reducing footwear is an effective strategy for the primary prevention of ulcers (Bus et al., 2008). Over recent years, there has been large growth in the number of individuals suffering with diabetes (Sicree and Shaw, 2007). It may therefore be appropriate to encourage all individuals with diabetes to wear pressure reducing footwear, irrespective of whether they are at high risk or not. This would ensure that all individuals with diabetes experience minimal plantar tissue damage would help protect individuals who do not attend for regular foot health checks against ulceration and would encourage patients to accept specialist footwear as normal health behaviour. However, for pressure reducing shoes to become the footwear of choice for low risk diabetic patients, they must be aesthetically acceptable so that they are actually worn (Knowles and Boulton, 1996).

One of the most effective designs for reducing in-shoe pressure is the rocker outsole (Hutchins et al., 2009a). With this type of footwear, a rocking motion of the foot is created which reduces the range of metatarsophalangeal joint motion and subsequent plantar pressure (Brown et al., 2004). There are two variations in this design: the traditional rocker and the curved rocker. Although both designs use a stiffened outsole, the traditional rocker has an outsole geometry incorporating a sharp apex, at approximately 55% of shoe length (Hutchins et al., 2009b), and rocking occurs about this point. In contrast, with the curved rocker shoe, the rocking motion is achieved with a gradually contoured outsole profile (Figure 1). Given that the curved rocker design can be manufactured to look more like conventional footwear, it

is more likely to be accepted by low risk patients, especially those who have not experienced foot problem severe enough to cause them to alter their footwear choices.

Traditional rocker design:



Curved rocker design:

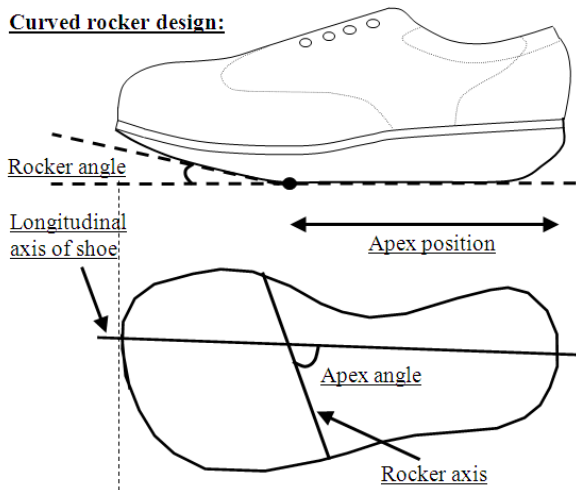


Figure 1: The traditional rocker design and the curved rocker design with the three design features: 1) rocker angle, 2) apex position and 3) apex angle.

The geometry of the curved rocker outsole can be characterised by three design features: 1) apex angle 2) apex position and 3) rocker angle (Figure 1). The rocker axis is a theoretical line across the shoe where the outsole begins to curve upwards. This axis can be moved proximally or distally (altering apex position) or angled differently with respect to the longitudinal axis of the shoe (altering apex angle). For a fixed apex position, the rocker angle is typically varied by increasing/decreasing the thickness of the outsole. In order to optimise the design of the rocker shoe, it is necessary to understand how each of the three outsole design features influence plantar pressure. Given that apex angle and apex position can be adjusted without any obvious change to the appearance of shoe, it is especially important to understand the effect of these parameters on plantar pressure across a range of different

individuals. It is possible that a single combination of apex angle, apex position and rocker angle may be optimal for all individuals and would therefore be the recommended design. However, it is also possible that different individuals may need different combinations of the three design features in order to maximise pressure reduction. In this scenario, in-shoe pressure measurement technology could be used, at the point of sale or in the clinic, to establish the most effective design for an individual patient.

To date, most studies aimed at investigating the capacity of rocker shoes to reduced pressure have simply compared peak pressure between two or three off-the-shelf shoes (Brown et al., 2004; Bus et al., 2009; Fuller et al., 2001; Nawoczenski et al., 1988; Praet and Louwerens, 2003; Schaff and Cavanagh, 1990). With this approach, it is not possible to understand the independent effect of the three design features which characterise outsole geometry: apex angle, apex position and rocker angle. There have been only two studies (Nawoczenski et al., 1988; van Schie et al., 2000) which have used a systematic approach to investigate the effect of these design features. However, both studies investigated healthy participants rather than people with diabetes, neither investigated the effect of varying apex angle and the study by van schie et al. (2000) investigated the less aesthetically acceptable traditional rocker shoe rather than the curved rocker shoe.

This study was undertaken as part of an EU funded project (SSHOES) which aimed to develop footwear to prevent foot problems associated with plantar pressure and diabetes. The project focussed specially on the needs of people early in the diabetes disease process. The aim of this study was to understand the effect of varying (1) apex angle, (2) apex position and (3) rocker angle (Figure 1) on plantar pressure in the curved rocker shoe. We sought to understand the mean effect of varying these three parameters in a cohort of low risk patients with diabetes and to establish whether the same effects would be observed in a healthy population. We also sought to understand whether a specific combination of the three design

features would be optimal for all individuals or whether different combinations may be required for different patients. This was addressed by describing inter-subject variability in the optimal value for each of three design features.

Methods

Participants

Following ethical committee approval, 24 volunteers with diabetes (14 males) and 24 healthy participants (17 males) were recruited at two sites: the University of Salford (UK) and the German Sport University (Germany). Participants were selected based on their shoe size (43 for men and 39 for women) and had to be able to walk unaided for a period of 45 min. Patients with diabetes were excluded if they suffered with any foot deformity. This was necessary as the shoes used in this study were all manufactured using a standard last because this helps maintain shoe aesthetics. Patients had a mean (SD) age of 57(8), a mean weight of 86.0(12.4) Kg and a mean height of 1.71 (0.09) m and healthy participants had a mean (SD) age of 49(15), a mean weight of 79.8(11.9) Kg and a mean height of 1.75(0.09)m.

Patients with diabetes were only included in the study if they did not demonstrate any serious neuropathy. The absence of neuropathy was assessed using two separate tests. Firstly, patients were required to sense a 10g monofilament at a minimum of 5 out of 6 sites on the plantar aspect of the foot (Feng et al., 2009). Secondly they had to be able to sense the vibration of a 128Hz tuning fork on the interphalangeal joint (Meijer et al., 2005). If patients were unable to detect more than one site or had absent vibration perception they were classed as neuropathic and not recruited for the study. Limiting the experimental work to low-risk patients with diabetes limits the generalisability of the findings. However, it was felt that this study would provide insight into the general principles of footwear design which could be incorporated into future footwear studies developed for high risk patients.

Footwear

All participants were required to walk in total of 12 pairs of rocker shoes plus one flexible control shoe which were manufactured specifically for the study by Duna®, Falconara Marittima, Italy. All shoes were made using the same last with a soft leather upper. In the control shoe, the outsole was manufactured from micro cellular rubber and this shoe had a bending stiffness similar to a running shoe (Figure 2a). For the rocker shoes (Figure 2b) the outsole was also constructed from micro cellular rubber and incorporated a 5mm thick piece of folex which created a very stiff outsole which did not flex. Different outsole geometries were produced for the rocker shoes using CAD CAM technology to ensure accuracy in apex location, orientation and rocker angle.

It was not feasible to cover every possible combination of apex angle, apex position and rocker angle due to the large number of shoes that would be required. Therefore we selected a typical curved rocker design with apex angle of 80°, apex position of 60% and rocker angle of 20° and attempted to understand the effect of varying each of the three design features around these reference values. A set of four rocker shoes was manufactured in which the apex angle was varied (70, 80, 90, 100°) and the rocker angle (20°) and apex position (60%) fixed (Figure 1). A second set of five shoes was then produced in which the apex position was varied (50, 55, 60, 65, 70% shoe length) and the rocker angle (20°) and the apex angle (80°) fixed. In the final set of five shoes, the rocker angle was varied (10, 15, 20, 25, 30°) and apex position (60%) and apex angle (80°) fixed. Although the shoe with the apex position at 60%, rocker angle 20° and apex angle 80° was included three times in the data analysis, it was only necessary to measure this shoe once.

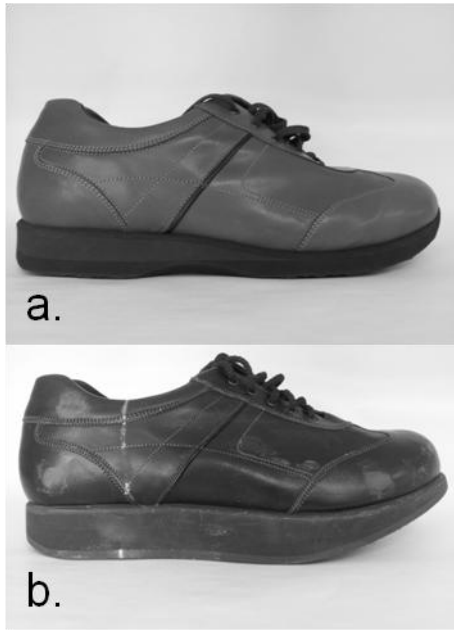


Figure 2: a) Control shoe and b) example rocker soled shoe used in the experiment. The rocker shoe had an 80° apex angle, 60% apex position and 20° rocker angle.

Data Collection

In-shoe plantar pressure was collected as participants walked at $1\text{m/s} \pm 10\%$ along a 20m walkway. Timing gates were used to ensure that participants walked within the defined speeds as walking speed has been shown to influence plantar pressure (Segal et al., 2004). All participants wore thin nylon socks during pressure testing and the order of shoes was randomised. This randomisation was carried out using a custom written Matlab program which generated a random sequence for each individual participant. Plantar pressure data was collected using a Novel Pedar system, (Munich Germany) (50Hz) with the pressure sensitive insole on top of a 3mm poron insole. A total of 25-35 continuous steps per shoe were obtained for each participant and the Pedar data exported into Matlab for processing.

For each participant, the shoe apex angle and apex position were expressed relative to both the shoe geometry and also foot anatomy using a line joining the 1st metatarsophalangeal joint (MTP) joint to the 5th metatarsal head (MTH) (“metatarsal break”). For this calculation

data were used from a single 3D foot scan (INESCOP, Spain) taken in normal standing and from measurements of the foot position within the shoe. Figure 3 illustrates how these design features were defined relative to foot anatomy.

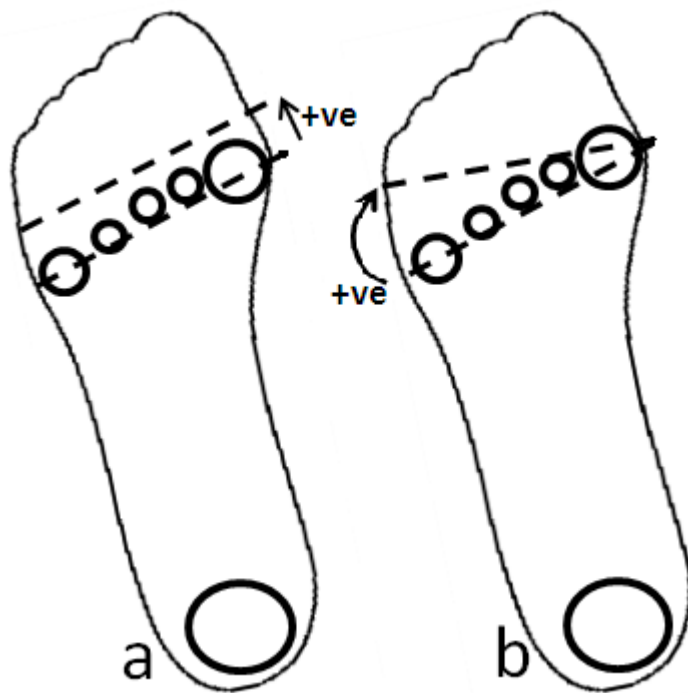


Figure 3: Apex position (a) and apex angle (b) relative to the metatarsal heads (MTH). Apex position, relative to the foot, was measured from the midpoint of the line joining the 1st-5th MTH (metatarsal break) and was normalised to shoe length. Apex angle, relative to the foot, was define relative to metatarsal break and expressed in degrees.

Data analysis and statistics

Peak plantar pressure during the stance phase of walking was used to characterise the effect of the three design features: apex angle, apex position and rocker angle. This outcome was calculated for 1) 1st MTP joint, 2) 2nd-4th MTH, 3) the hallux, 4) 5th MTH and 5) the heel. The first three are the plantar regions at greatest risk of ulceration (Weijers et al., 2003) and were defined following Cavanagh et al. (1994). Peak plantar pressure was calculated for each

of the four regions for each of the 25-35 steps in each shoe. It was then averaged across all steps to give a single value for each region and shoe. The analysis (described below) of the left and right data showed the same trends and therefore only the left side data is presented here. Although it is possible to report pressure time integral in addition to peak plantar pressure, a recent review concluded that the added value of this parameter is limited (Bus and Waaijman, 2012) and therefore it has not been presented.

Two-way repeated-measures ANOVA testing was used to understand mean effects. Specifically, we tested for (1) main effects of varying each of the three design features (2) main effects of group (healthy and diabetic) and finally (3) interaction effects, i.e. whether the effect of the footwear differed between the two groups. A separate ANOVA test was conducted for each design feature (plus the flexible control shoe) in each anatomical region with a significance level of $p=0.05$. Further Bonferroni post hoc testing was then used to examine any significant main effects of design features.

In order to quantify inter-subject variability, the apex angle which gave the minimum peak pressure was identified for each participant in each of the four anatomical regions. This data was then used to calculate the distribution of optimal apex angles (across individuals) for each anatomical region. This analysis was repeated for apex position and rocker angle.

Results

Mean effect of the different rocker shoe designs:

There were a number of significant main effects for footwear design features (Figure 4) and significant differences between the control shoe and the individual rocker shoes (Table 1). When the apex angle was increased from 70° to 100° there was a corresponding reduction in pressure under the 1st MTP joint (Figure 4a), with a maximum pressure reduction of 14% in

comparison to the control shoe (100° condition). However, only minimal differences were observed in the 2-4th MTH and hallux regions (Figure 4b-c) between the shoes with differing apex angles. The biggest reduction in pressure relative to the control shoe (39%) was observed in the 2nd-4th MTH regions (80° condition) but minimal reductions were observed in the hallux and MTH5 regions. In contrast to the other regions, pressures increased in the heel region relative to the control shoe, but again there was a little change across the different apex angles.

	Apex Angle (Degrees)				Apex Position (% of shoe length)					Rocker Angle (Degrees)					233
	70	80	90	100	50	55	60	65	70	10	15	20	25	30	
1st MTP			R	R											235 236
2nd-4th MTH	R	R	R	R	R	R	R	R	R	R	R	R	R	R	237 238
Hallux			R						I	I	I				239
5th MTH	R	R			R	R	R					R	R	R	240 241
Heel	I	I	I	I	I	I	I					I	I	I	242

Table 1: Significant differences between control shoe and the rocker shoe design features for the 5 plantar regions. “R” denotes significant reduction, “I” denotes significant increase.

When the apex position was varied from 50 to 70% there was no clear trend in peak pressure in the 1st MTP region (Figure 4a). However, in the 2nd-4th MTH, hallux and 5th MTH regions, pressures were observed to be higher for the shoes with apex positions further forward in the shoe (Figure 4b-d). In comparison to the control shoe, a maximum pressure reduction of 13% was observed under the 5th MTH, however a 39% reduction was observed under the 2nd-4th MTH but there was no difference in peak pressure in the hallux region between the control and any of the shoes with varying apex position (Table 1). In the heel region, shoes with an apex position further back were observed to significantly increase peak pressure relative to the control shoe (Figure 4e & Table 1).

As rocker angle was increased from 10 to 30° there was a decrease in peak pressure under the 5th MTH and an initial decrease followed by a plateau under the 2nd-4th MTH (Figure 4b). However, although a similar trend was observed under the 1st MTP joint, the differences between the different rocker angles were relatively small. In the hallux regions the lower angle designs actually increased pressure relative to the control shoe (Figure 4c & Table 1). Peak pressures were again observed to increase in the heel region with the higher angle designs.

There was a significant effect of group ($p < 0.05$) only in the 2nd-4th MTH regions with the control subjects having lower peak pressures than the patients with diabetes. However, with the exception of the apex angle in the hallux region, there were no design features by

group interactions, meaning that the effect of varying the footwear features was the same for the patients with diabetes as it was for the control subjects.

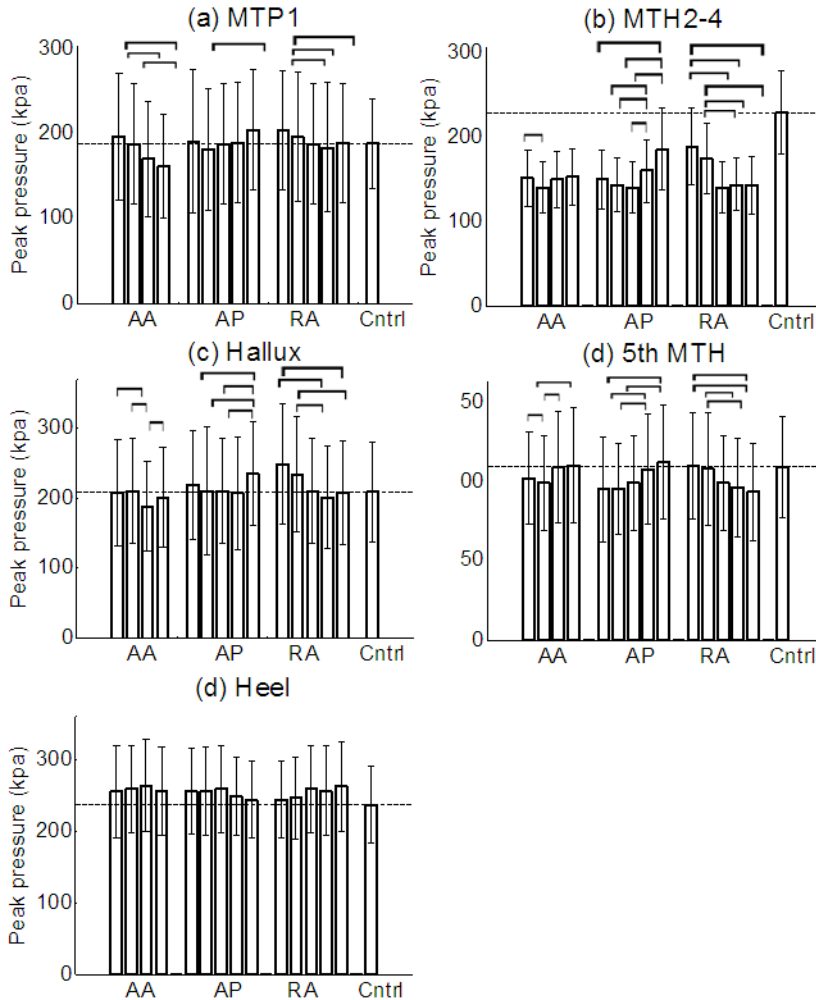


Figure 4: Histograms to show mean peak pressure for varying apex angle (AA=70, 80, 90 & 100° from left to right), apex position (AP=50, 55, 60, 65 & 70%) and rocker angle (10, 15, 20, 25 & 30°) for each of the different anatomical regions (a-d). The horizontal dotted line represents the pressure from the control shoe. The horizontal lines indicating pairings on each graph indicate significant differences between footwear conditions ($P<0.05$ with Bonferroni correction). Significant differences between the control and a specific design of rocker shoe have been identified with a ‘*’ at the base of the bar.

Inter-subject variability between the different rocker shoe designs

In order to understand inter-subject variability associated with the effects of varying the design features, and given the absence of design feature by group interactions, the data from all subjects was pooled ($n=48$) and has been presented in Figure 5. The effect of apex angle showed the least inter-subject variability of the three design features; however the mean optimal apex angle differed across regions, being larger (90 or 100) for pressures in the 1st MTP joint and hallux regions and lower (70 or 80) for pressures in the 2nd-4th MTH and 5th MTH regions (Figure 5 & Table 2).

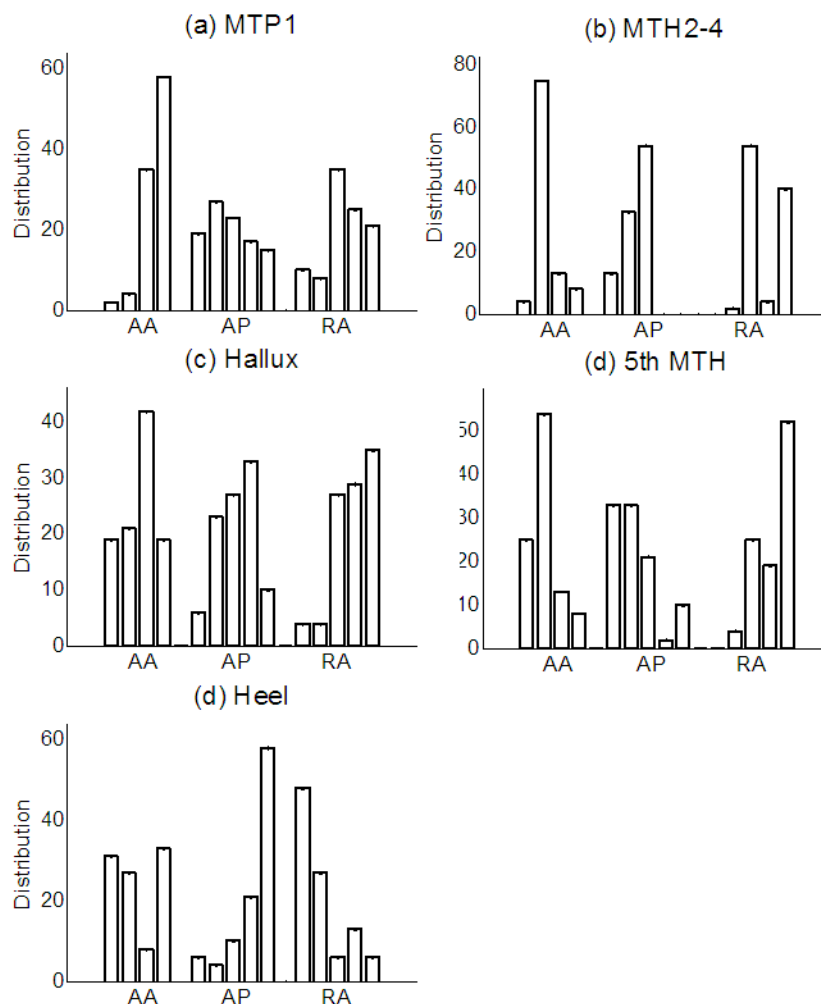


Figure 5: Histograms to show the relative distribution (%) across all 48 participants of optimal apex angle (AA=70, 80, 90 & 100° from left to right), optimal apex position (AP=50,

55, 60, 65 & 70%) and optimal rocker angle (10, 15, 20, 25 & 30°) for each of the different anatomical regions (a-e).

Optimal apex position demonstrated a high level of inter-subject variability in the 1st MTP joint and hallux regions, with no clear optimal position. However, in the other two forefoot regions, the optimal apex position was almost always between 50 and 60% (Table 1). the participants. Although optimal rocker angle displayed some inter-subject variability in the forefoot regions, rocker angles of 10° or 15° were rarely found to be optimal. This again contrasted with the heel region where the lower angles performed better.

	1st MTP	2-4 MTH	Hallux	5th MTH	Heel
Optimal AA (shoe)	95(6.8)	82.5(6.7)	86(10.1)	80.4(8.5)	84.4(12.5)
Optimal AA (foot)	18.8(6.2)	5.5(7.6)	9.8(9.4)	3.6(9.3)	7.8(14)
Optimal AP (shoe)	59.1(6.7)	57.1(3.5)	60.9(5.5)	56.1(6.2)	66(5.9)
Optimal AP (foot)	- 17.5(25.8)	- -22.7(24.7)	- -11.7(29.3)	- 25.3(31.2)	- 3.3(27.2)
Optimal RA (shoe)	21.9(6.1)	24.1(5)	24.4(5.4)	25.9(4.8)	15.1(6.4)

Table 2: Mean (SD) optimal values for apex angle (AA), apex position (AP) and rocker angle (RA), expressed both relative to the shoe and relative to the foot.

Discussion

The purpose of this study was to understand the effect of varying apex angle, apex position and rocker angle on peak plantar pressure in a curved rocker shoe. Our analysis demonstrated differing effects of the three features between the different anatomical regions. Highest pressure reductions (39%) were observed in the 2nd-4 MTH regions and, in these regions, both low rocker angles ($<20^\circ$) and anterior apex positions ($>60\%$ shoe length) increased pressures, however, the apex angle had little effect on peak pressure. Similar trends were observed in the 5th MTH region. In the hallux region, provided lower rocker angles ($<20^\circ$) were excluded, peak pressures were very similar across the different shoe designs. The only exception was a modest reduction in peak pressure in the shoe with a 90° apex angle. Similarly, in the 1st MTP region, peak pressures seemed relatively unaffected by apex position and rocker angle. However, there was a clear decrease in pressure as apex angle was increased to 100° . Finally, in the heel region, small increases in peak pressure were observed across all designs.

One of the objectives of this study was to establish some general design principles which could be incorporated into preventative rocker shoes. It was not possible to cover every possible combination of design feature and thus we cannot make definitive recommendations. However, the results suggest that rocker angles of $<20^\circ$ should be avoided along with apex positions of $>60\%$ shoe length. Furthermore, given that we tested four shoes with a rocker angle of 20° , apex position of 60% and varying apex angle, we can make some provisional recommendation for apex angle. Ulceration is less common under the 5th MTH and therefore we suggest the shoes should be designed to prioritise offloading across the three forefoot regions. The 2nd-4th MTH regions were unaffected by apex angle and therefore we suggest a 95° angle as a compromise for the 1st MTP region and the hallux.

Another objective of the study was to establish whether different combinations of design features may be required for different patients. Optimal values of each of the design features varied across individuals suggesting that the use of individually tailored outsole geometries would give improved offloading compared to a one-design-suits-all approach. Expressing apex position relative to the metatarsal break instead of the shoe (Figure 4) did not reduce the level of variability (Table 2). This suggests that differences between participants cannot be attributed to differences in the foot position within the shoe. Instead, it is possible that these differences are the result of structural (Cavanagh et al., 1997) or biomechanical variability between people (Morag and Cavanagh, 1999). For example, it is possible that differences in the range of motion at specific joints or the foot progression may have resulted in varied responses to varying the footwear design features. However, irrespective of the mechanism, this study demonstrates that in-shoe pressure testing in a shop or clinic should be considered when deciding on the best rocker shoe design for an individual patient.

For this study, we recruited low risk patients with diabetes who did not have foot deformity or serious neuropathy. This choice was driven by our focus on improving footwear for those in the early stages of diabetes. However, this limits the generalisability of our finding to high risk patients. Despite low levels of neuropathy in our diabetes cohort, we observed differences in plantar pressure in the 2nd-4 MTH regions, suggesting disease-related changes independent of neuropathy (e.g. increased joint stiffness (Sacco et al., 2009)). However, despite these differences, the effect of varying each footwear feature was almost the same between the groups. Studies have shown that neuropathy can affect gait (Sawacha et al., 2009), and possibly plantar pressure, therefore future work might focus on a group more affected by sensory loss. Nevertheless this study has provided important insight into the

effects of outsole geometry on plantar pressure and the results can be used to inform future footwear studies involving high risk patients.

Two other studies have investigated the effect of outsole geometry on plantar pressure (Nawoczinski et al., 1988; van Schie et al., 2000). Van Schie et al. (2000) also found that apex position may need to be individually adjusted to maximise offloading. However, in contrast with our findings, they observed that increasing the rocker angle from 20 to 30°, continued to reduce pressure. This may be a difference between curved rocker shoes and the traditional rocker design.

Nawoczinski et al (1988) investigated the curved rocker design, but used the parameters of “takeoff point” and sole radius of curvature to parameterise outsole properties. They found that a takeoff point at 50% shoe length reduced pressures under the 3rd MTH compared to a takeoff point at 60%. This may correspond to our observed minimum pressure at apex positions 55-60% (Figure 4 & 5). Nawoczinski et al (1988) also found that pressure decreased with increasing radius of curvature (increased rocker angle).

There are some limitations to the present study. Firstly, in order to test the relatively large numbers of shoes used in this study, participants were only given a few minutes to become accustomed to each different design. However, pilot work showed that peak pressures in rocker shoes typically stabilise after a short amount of time. Therefore, we believe the data collected is representative of pressure patterns which would be observed in a real-world scenario. The second limitation is that we did not study the interaction between the different design features. However, in order to study all possible interactions, it would be necessary to test in excess of 100 shoes on each participant. This would be practically infeasible and therefore future studies are required, with a different range of designs, to build on the knowledge generated in this study. A final limitation is that, although two separate

tests were used to screen out patients with neuropathy, it is possible that a small number of patients with low levels of neuropathy may have been included. However, this is arguably a characteristic of our target group of low risk patients with diabetes.

Conclusions

This is the first study aimed at understanding the effect each of the design features which characterise the outsole geometry of a curved rocker shoe. Although not definitive recommendations, the results suggest that low rocker angles ($<20^\circ$) and anterior position and apex position ($> 60\%$ of shoe length) should be avoided. Furthermore, the results suggest that an apex angle of 95° could balance offloading across the forefoot and hallux, the regions most susceptible to ulceration. Further work is required to understand whether the findings of this study can be generalised to high-risk patients. This work is an essential step which must be carried out before any future large-scale trials are used to test the efficacy of therapeutic footwear in the reduction/prevention of ulceration.

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